K091546
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510(k) Summary

JUN 24 2009

Noras OR Head Coil 3T

Date of Summary Preparation: April 30, 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

1. General Information

Importer/Distributor
Name and Address
Noras MRI products GmbH
Leibnizstr.4
97204 Hoechberg / Germany

ERN: 3004929307
Owner/Operator Number: 9071737

Manufacturing Site
Name and Address
Noras MRI products GmbH
Leibnizstr.4
97204 Hoechberg / Germany

ERN: 3004929307
Owner/Operator Number: 9071737

2. Contact Person

Zahed Sedighiani
Regulatory Affairs Manager
Noras MRI products GmbH
Leibnizstr.4
97204 Hoechberg
Germany
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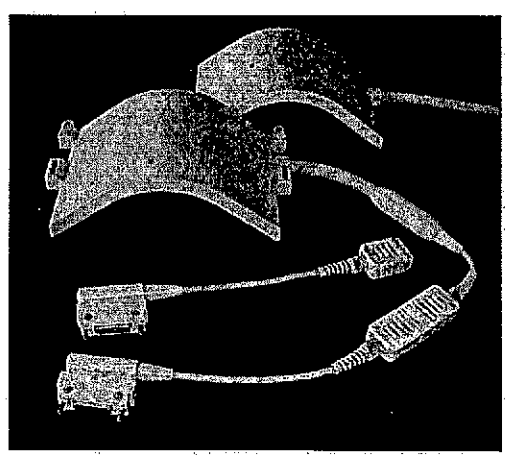
3. Device Name and Classification

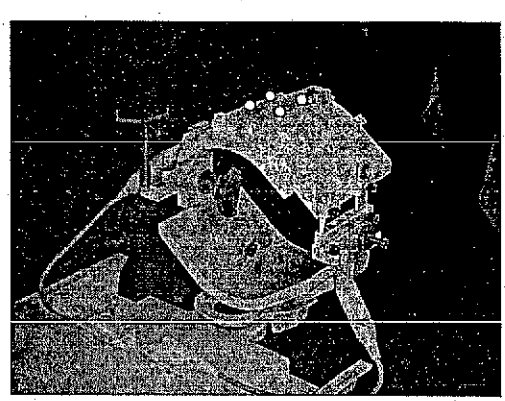
Trade Name:	**OR Head Coil 3T**
Common Name:	**OR Head Coil 3T**
Classification Name:	Magnetic Resonance Diagnostic Device
Classification Panel:	Radiology
CFR Number:	21 CFR § 892.1000
Device Class:	II
Product Code:	90MOS

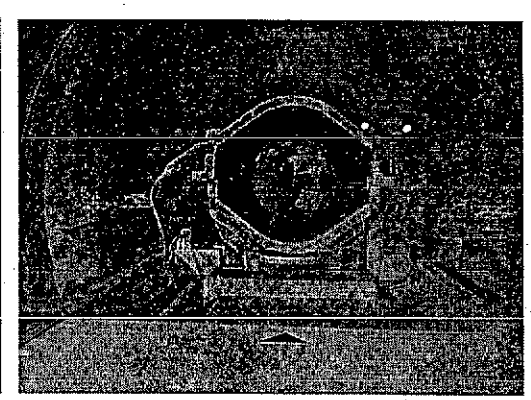
4. Device Description

The **Noras OR Head Coil 3T** is an 8-channel phased array coil. The coil is divided into a bottom and a top array of 4 channels each. Each channel is tuned to the Larmor frequency of the 1H spin in a magnetic field of 3T, 123.2 MHz. Each coil is connected to the MAGNETOM system by a separate cable.



Use of the **Noras OR Head Coil 3T** requires the **Noras OR Head Holder** (K071179 April 30, 2007). The pictures below show the complete set.





5. Intended Use

The intended use of the **Noras OR Head Coil 3T** is the MR examination of the human brain just before, during and at the end of the brain surgery in the operating room. It can also be used as a standard diagnostic head coil for diagnostic examinations and fMRI.

6. Substantial Equivalence

Noras MRI products GmbH believes that, within the meaning of the Safe Medical Devices Act of 1990, the 8-channel phased array **Noras OR Head Coil 3T** for the Magnetom Systems is substantially equivalent to the following coil:

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Product Code	Comparable Properties
Noras OR Head Coil 1,5T	K060758	March 21, 2006	90MOS	Proton imaging
MRI Devices Corporation (now known as Invivo Corporation) High Resolution Head Coil Model HRH-63-8	K013159	October 16, 2001	90MOS	High Resolution Head Imaging fMRI

7. Summary of Technological Characteristics of the Principal Device as Compared with the predicate Device

Although the MRI Devices High Resolution Head Coil is limited for use outside the operating room, we believe that all top coils are substantially equivalent.

8. General Safety and Effectiveness Concerns

The **Noras OR Head Coil 3T** will conform to the FDA recognized NEMA Standards for the measurement of performance and safety parameters and the IEC standards for safety issues with the Magnetic Resonance Imaging Devices, IEC 60601-2-33:2002. This will assure that the performance of this device can be considered safe and effective when used with the currently available MAGNETOM 3T systems Trio a Tim and Verio.

The NEMA Tests can be found in Appendix C. The NEMA Tests were done on software platform version VB15A. We have included the Common Risk Analysis for syngo MR2006A, which is the same functionality as syngo platform MR 2004A. We believe the NEMA tests on Trio a Tim are applicable to Verio system.

9. Conclusion as to Substantial Equivalence

Noras MRI products GmbH believes that, within the definition of the Safe Medical Devices Act of 1990, the 8-channel phased array **Noras OR Head Coil 3T** is substantially equivalent to the predicate device listed above.

Hubert Noras
President

30.04.09
April 30, 2009

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2009

Mr. Zahed Sedighiani
Regulatory Affairs Manager
Noras MRI Products GmbH
Leibnizstr. 4, Hoechberg 97204
GERMANY

Re: K091546
Trade/Device Name: Noras OR Head Coil 3T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: April 30, 2009
Received: May 27, 2009

Dear Mr. Sedighiani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091546

Device Name: **Noras OR Head Coil 3T**

Indications for Use:

The intended use of the **Noras OR Head Coil 3T** is, in conjunction with a Magnetic Resonance Scanner, the MR examination of the human brain just before, during and at the end of the brain surgery in the operating room. The coil can also be used as a standard diagnostic head coil for diagnostic examinations and fMRI (Functional Magnetic Resonance Imaging).

Used in the 3T MAGNETOM Systems, it is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures of the head.

When interpreted by a trained physician, these images provide information that can be useful in determining diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091546